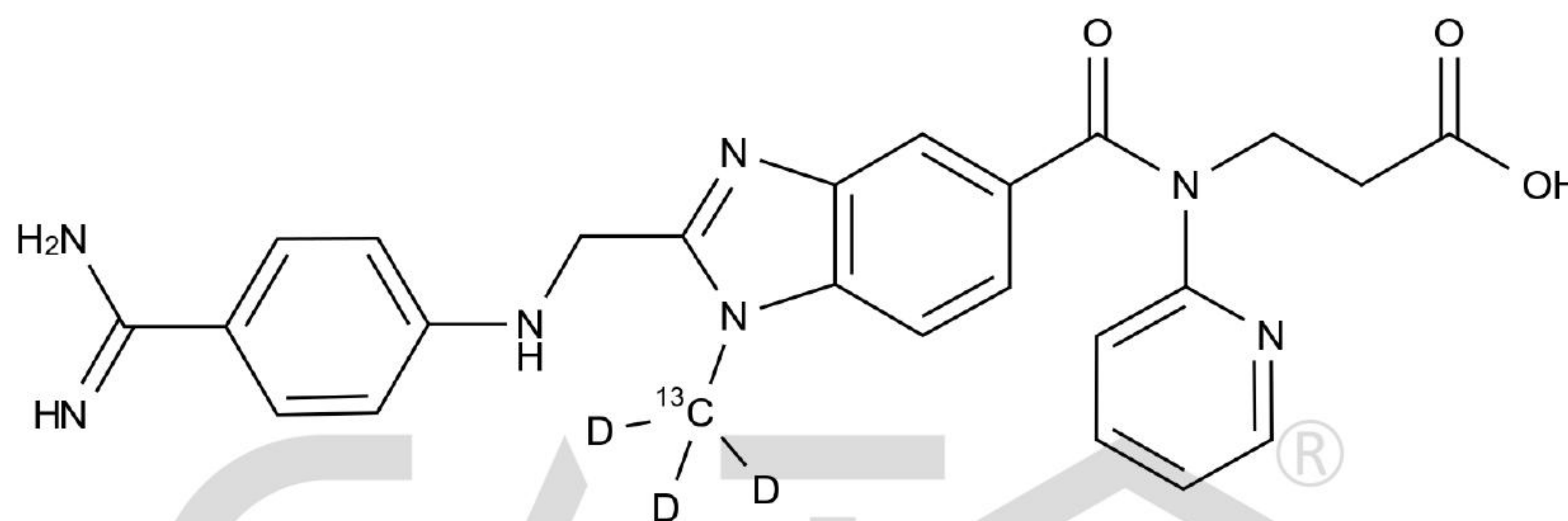


Certificate of Analysis

Reference Material

Product Name:	Dabigatran-13C-d3	Catalogue Number:	C4X-108981
Chemical Name:	N/A	Lot Number:	0313-RE-0033
CAS Number:	N/A	Expiry Date:	Jan 26, 2026
Molecular Formula:	C ₂₄ [¹³ C]H ₂₂ D ₃ N ₇ O ₃	Storage:	2°C ~ 8°C Protected from light and Sealed
Molecular Weight:	475.52		

Chemical Structure:



Test Items	Method	Results
Appearance	Visual inspection	White to Off-White Solid
Identification	LCMS&IR&HNMR	Confirmed
Chemical Purity	HPLC	97.99%
Isotopic Purity		99.5% D; 99.0% ¹³ C
Water Content	Karl Fischer	3.8%
Residual Solvents	NMR	0.3% ethanol
Assay		94.0%

Comment:

The calculation of the 100% method follows the formula (calculated on the non-dried basis):

Assay (%) = (100% - Water Content - Residual Solvents) * Purity HPLC (%) / 100%

Water Content and Residual Solvents are considered as absolute effect, HPLC purity is considered as relative effect.

Signature:

Prepared by:

Nacy

Reviewed by:

Xenia

Aporoved by General manager:

David

Date: Jan 27, 2023

Date: Mar 16, 2023

Date: Mar 16, 2023

